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(54) High frequency oscillation patient ventilator system

(57) A patient ventilator system (19) comprises a high frequency oscillation ventilator (1,4,5,6) connectable to a patient circuit (2,3) and operable to induce oscillations within gas in the circuit (2,3) at a predetermined high frequency and a gas supply (7) connectable to the patient circuit (2,3) for supplying breathing gas thereto; A detection device (14,15,16) is also included within the ventilator system (19) and is adapted to monitor during the operation of the high frequency oscillator ventilator (1,4,5,6) one or both gas pressure and gas flow to detect a variation therein not derived from the induced high frequency oscillations and to output a trigger signal (13) dependent on the detected variation indicating a spontaneous breathing effort; and in that gas supply (7) is operable on receipt of the trigger signal (13) to supply breathing gas into the circuit (2,3) at a level to assist the spontaneous breathing effort.

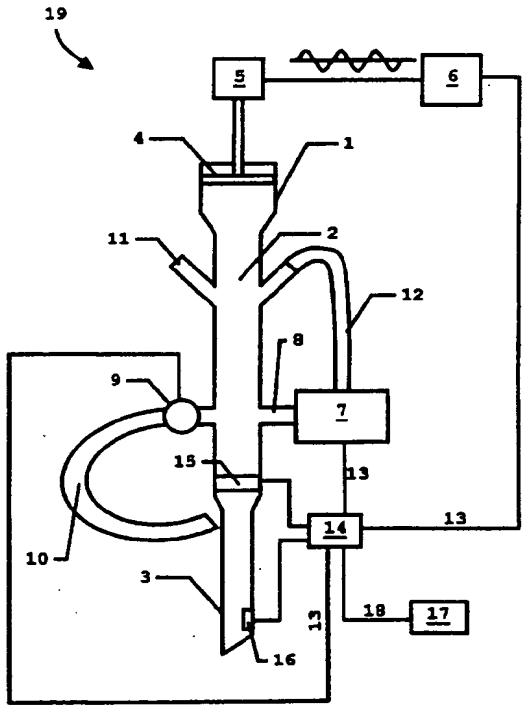

Fig. 1

EP 1 106 197 A2

Description

High Frequency Oscillation Patient Ventilator System

[0001] The present invention relates to a high frequency oscillation (HFO) patient ventilator system, in particular to an HFO system capable of providing an assisted ventilation support of a spontaneous breathing effort and also to a monitoring device capable of detecting a spontaneous breathing effort during HFO ventilation.

[0002] An HFO ventilator supplies breathing gas to the airways of a patient via a patient circuit at a frequency of approximately 150 breaths per minute or more and with tidal volumes significantly less than required during spontaneous breathing, typically at or below anatomical dead-space volumes. This is in marked contrast to a conventional mechanical ventilator which typically supplies breathing gas to the patient circuit at a frequency and with a tidal volume close to the values during spontaneous breathing.

[0003] HFO ventilators are well known and generally comprises an oscillator which is connectable in gas communication with one end of the gas tubing of a patient circuit. The circuit terminates in an opposite end, such as in an endotracheal tube, for connection to a patient's airways. The oscillator is then driven to vibrate a column of gas within the circuit to actively supply gas to and extract gas from the patient's airway. The HFO ventilator also comprises a gas supply for providing a constant, continuous so called 'bias' flow to the patient. This bias flow intersects the oscillatory pathway and serves to maintain (bias) a mean positive airway pressure about which the high frequency oscillations generated by the HFO ventilator occurs and also to wash exhaled gasses from the circuit. Gas leaves the circuit through an expiratory limb, which is designed as a low pass filter. The bias supply of such systems is usually insufficient to supply sufficient gas to a patient if the patient should attempt a spontaneous breath.

[0004] One known patient ventilator system, which reduces this problem, is disclosed in US 5,165,398. The system comprises an HFO ventilator and a conventional mechanical ventilator connected to a patient breathing circuit and cooperable to provide, in one mode of operation, a conventional low frequency, large tidal, volume time cycled mechanical ventilator supply having superimposed thereon high frequency oscillations from the HFO ventilator. In another mode of operation this system can act as an HFO ventilator with the conventional mechanical ventilator providing the continuous bias flow at a level to maintain a constant pressure. A mechanical pressure regulator is provided in the patient circuit proximal the patient end which operates to increase this continuous bias flow and maintain the pressure as a patient attempts to breath spontaneously. A non-assisted spontaneous breathing support mode of operation is thereby provided.

[0005] According to a first aspect of the present invention there is provided a patient ventilator system capable providing assisted support of a spontaneous breathing effort detected during high frequency oscillation ventilation. Thus, by monitoring for changes in one or both of the gas pressure and gas flow during the operation of an HFO ventilator which are unrelated to the high frequency oscillations produced by that ventilator, a spontaneous breathing effort can be detected and a gas supply, preferably a conventional mechanical ventilator, can be operated to supply breathing gas at a level to assist the detected spontaneous breathing effort.

[0006] According to a second aspect of the present invention there is provided a detection device adapted to monitor for changes in one or both of the gas pressure and gas flow during the operation of an HFO ventilator which are unrelated to the high frequency oscillations produced by that ventilator and to provide an output signal dependent on the monitored changes to indicate one or more of a spontaneous breathing effort, a leak and hyperinflation.

[0007] An exemplary embodiment of the invention will now be described with the reference to the drawings of the accompanying figures of which:

[0008] Fig. 1 shows a schematic representation of a patient ventilator system according to the present invention connected to a patient circuit.

[0009] Considering now Figure 1, an oscillator unit 1 is connected to a patient circuit 2, which terminates at its opposite end in an endotracheal tube 3. A piston 4 is reciprocally movable within the oscillator unit 1 by a bi-directional motor 5. The motor 5 is driven in response to a variable frequency, variable period and amplitude wave drive pulse train (typically square or sine wave) output from a signal generator 6. The signal generator 6 is able to provide a pulse train typically as a continuous square or sine wave at variable frequency of approximately 3Hz and above to the motor 5 which then operates to reciprocate the piston 4 at that frequency. The generator 6 is also provided with controls to vary the amplitude of the pulse train, which in turn varies the stroke length of the piston 4, and to vary the duration of the positive and the negative going periods of the pulse train, which coincides with the inspiration to expiration ratio.

[0010] The thus driven piston 4 will, during each cycle of the drive pulse train, alternately produce a positive and a negative pressure in breathing gas within the circuit 2 relative to the static airway pressure of a patient who is connected to the circuit 2 with the endotracheal tube 3. This will cause breathing gas to be moved into and extracted from the patient's airways at a high frequency determined by the output from the signal generator 6. A breathing gas supply 7 is also provided to supply a continuous bias flow through the conduit 8 to intersect the oscillating column of gas within the circuit 2 and exits through a valve 9 and a low pass filter 10. By controlling one or both of the bias flow rate and the opening of the valve 9 the static airway pressure can be main-

tained at a suitable level above ambient. The low pass filter 10 is designed to inhibit the escape of breathing gas from the system which carries the high frequency oscillations induced by the movement of the piston 4. Gas which is extracted at the high frequency set by the signal generator 6 will instead escape from the circuit 2 through an expiration port 11 to be passed either to atmosphere (as shown in Figure 1) or recovered for later disposal or re-circulation in a manner known in the art. It will be appreciated by those skilled in the art that the above described components cooperate to provide an example of a high frequency oscillation (HFO) ventilator of the type generally known in the art and that the piston oscillator arrangement 1,4,5 may be replaced with other known means for inducing oscillations within the patient circuit 2,3 of a HFO ventilator such as a pneumatic oscillator or an electro-magnetic oscillator (for example a loudspeaker).

[0011] The gas supply 7, as well as providing the bias flow for the HFO ventilator, also operates as a conventional mechanical ventilator to supply breathing gas into the patient circuit 2 via conduit 12 in an amount substantially equivalent to that required during spontaneous breathing and at a pressure to cause substantial inflation of the patient's lungs. Switching of the gas supply 7 between bias supply and conventional mechanical ventilation is controlled by a trigger signal 13 from an analyser 14, as is the operation of the valve 9 and the signal generator 6, as will be described below. The analyser 14 is operably connected to receive output signals from a flow sensor 15 and pressure sensor 16, the latter being preferably located in use as close to the patient's airways as practicable - here shown mounted at the open end of the endotracheal tube 3 - so as to be better able to measure the small pressure changes induced by a spontaneous breathing effort. An optional alarm unit 17 may also be connected to receive a signal 18 from the analyser 14 in the event of abnormal operating conditions of the ventilator system 19 being detected by the analyser 14 and to provide a sensible alarm signal in dependence thereof.

[0012] In use the above described patient ventilator system 19 operates by default as an HFO ventilator the output of which is controlled by the drive pulse train from the signal generator 6. When a spontaneous breathing effort by a patient is detected by the detection device (analyser 14 and gas sensors 15,16) the analyser 14 provides the trigger signal 13 which closes the valve 9, varies the output from the signal generator 6 to reduce or remove high frequency oscillations from the gas in the circuit 2 and which switches the operating mode of the gas supply 7 to one of a conventional mechanical ventilator. In this mode the gas supply 7 functions to provide one or other of a time, pressure or volume controlled delivery of breathing gas to assist the detected spontaneous breathing effort of a patient. Such parametric delivery control in support of a patient breathing effort is well known in the art of conventional mechanical ventilation and is described for example in US 5,937,853, the contents of which is included herein by reference. The so described gas supply 7 comprises a gas delivery unit and a regulating unit arranged to control the gas delivery unit to deliver gas to a patient according to prescribed parameter values. Sensors are disposed within the ventilator gas conduits to sense breathing efforts of the patient and to control the regulating unit in order to adapt gas delivery to deliver a pressure or volume support to the breathing effort of the patient to a predetermined total volume or pressure level. Such a ventilator is able to provide one of Pressure Supported Ventilation, Volume Supported Ventilation and Volume Supported Ventilation- Volume Controlled Ventilation in response to the sensed breathing effort.

[0013] The gas supply 7 continues to operate as a conventional mechanical ventilator to provide one or other of the support modes described above for a predetermined period of time after which it reverts to delivery of a bias flow through the conduit 8. The time period may be set for example within the gas supply 7 or within the analyser 14. In the latter case a signal will be passed from the analyser 14 to the gas supply 7, the valve 9 and the signal generator 6 to restore the HFO ventilator functions of these items 6,7,9. Alternatively these items 6,7,9 may be configured to operate the ventilator system 19 to provide conventional mechanical ventilation for so long as a trigger signal 13 is present so that in the latter case removal of the trigger signal 13 by the analyser 14 after the predetermined period of time returns the ventilator system 19 to its default operation as an HFO ventilator. The predetermined period of time may be varied according to the frequency with which spontaneous breathing efforts are detected during HFO ventilation and the analyser 14 may be further adapted to permanently switch the operating mode of the gas supply 7 to the one of conventional mechanical ventilator if the frequency of spontaneous breathing efforts increase above a threshold value set dependent on the clinical application of the ventilator system 19.

[0014] An example of the detection device according to the present invention is shown in Figure 1 and here comprises a separate flow meter 15 and a pressure sensor 16 (these may be provided as a unitary gas sensor providing both measurement functions) and an analyser 14 which includes a suitably programmed microprocessor adapted to carry out the pressure and/or flow signal analysis described below in order to detect abnormal operating conditions of the ventilator system 19.

Mean Periodic Pressure

[0015] This is defined herein as the average pressure proximal the patient's airways over one cycle of the high frequency oscillations generated during high frequency oscillation ventilation.

[0016] As a patient attempts to draw a breath (spontaneous breathing effort) the mean periodic pressure

will reduce. The analyser 14 can be adapted to detect a spontaneous breathing effort by monitoring the pressure detected by the sensor 16 during the operation of the HFO ventilator and calculating the mean periodic pressure. The analyser 14 then operates to analyse the calculated mean periodic pressure to determine when the calculated value falls below a pre-set value and to output the trigger signal 13 indicating a detected spontaneous breathing effort.

[0017] However, a gas leakage within the ventilator system 19 would also result in a pressure reduction measured by the pressure sensor 16 and false detections of spontaneous breathing efforts by the analyser 14. In order to reduce the occurrences of false detections the analyser 14 may be further adapted to carry out a time trend analysis of the calculated mean periodic pressure. That is, to analyse the mean periodic pressure to determine whether or not there is an increase in divergence of the calculated value from the trigger level over a number of cycles of the high frequency oscillations. If there is then this indicates that the pressure is continuing to reduce so that a spontaneous breathing effort is more likely than a leakage. Conversely, if a leakage is determined to be the more likely cause of the pressure reduction the analyser may be adapted to provide the output signal 18 to the alarm 17.

Mean Periodic Flow

[0018] This is defined herein as the average flow over one cycle of the high frequency oscillations generated during high frequency oscillation ventilation.

[0019] The mean periodic flow depends on the inspiration to expiration ratio set by the waveform output from the signal generator 6 and for a 1:1 ratio the value of the mean periodic flow will be zero. A spontaneous breathing effort will be characterised by an increased flow towards the patient. Thus the analyser 14 may be adapted to monitor the pressure detected by the sensor 16 during the operation of the HFO ventilator and calculate the mean periodic flow. The analyser 14 is then further adapted to analyse the calculated mean periodic flow to determine when the calculated value exceeds a threshold value (for example zero) and to output the trigger signal 13 indicating a detected spontaneous breathing effort.

[0020] However, an increased flow towards the patient may also indicate a leakage or hyperinflation and lead to false detections of spontaneous breathing efforts by the analyser 14. A pressure increase is associated with hyperinflation so by configuring the analyser 14 to also monitor the pressure sensed by the pressure sensor 16 and to calculate the mean periodic pressure therefrom false detections due to hyperinflation may be reduced. The analyser 14 can then provide the trigger signal 13 to indicate a detection of a spontaneous breathing effort if there is determined to be both an increase in mean periodic flow and no increase in mean periodic pressure or the alarm signal 18 to indicate the presence of hyperinflation if the increase in flow is accompanied by an increase in pressure.

[0021] To further reduce the occurrence of false detection of spontaneous breathing efforts a time trend analysis of the calculated mean periodic pressure may be made to determine whether or not a leak is present and the trigger signal 13 or the alarm signal 18 provided also in dependence of the time analysis, as discussed above.

[0022] Alternatively a time trend analysis of the calculated mean periodic flow may be carried out by the analyser 14 to determine whether or not the calculated value stabilises over a number of periods. The trigger signal 13 will be output by the analyser depending on the mean periodic flow exceeding a trigger value and the presence of a continued increase of the mean flow, otherwise the alarm signal 18 may be provided.

Tidal Volume

[0023] The total amount of breathing gas (tidal volume) provided by the oscillating piston 4 during an inspiration phase (inspiratory tidal volume) and an expiration phase (expiratory tidal volume) of an oscillatory cycle during high frequency oscillation ventilation can be analysed within the analyser 14 and a detection of a spontaneous breathing effort made based on this analysis. Knowledge of the duration of the positive and negative going periods of the drive pulse train output from the signal generator 6 allows the analyser 14 to calculate the expected inspiration tidal volume and expiration tidal volume. In the event of a spontaneous breathing effort the inspiration tidal volume will increase and the expiration tidal volume remain constant and if a leakage is present the inspiration tidal volume will remain substantially constant and the expiration tidal volume decrease. Adapting the analyser 14 to monitor both tidal volumes will allow the analyser to detect a spontaneous breathing effort and differentiate this from a leakage.

[0024] In all configurations of the analyser 14 needed to provide one or more of the above described analyses information on the frequency and the duration of the positive and negative going periods of the drive pulse train, hence respectively the oscillating frequency of the gas within the circuit 2 and the inspiration to expiration ratio, may be manually input into the analyser 14 using an associated input device (not shown) such as a computer keyboard or a dedicated keypad, or may be passed to the analyser 14 directly from a suitably adapted signal generator 6.

[0025] It will be appreciated by those skilled in the art that from the above discussion one or other of the gas flow meter 15 and the pressure sensor 16 can be omitted from the detection device of the present invention, depending on the intended operation of the detection device. Moreover, it will be appreciated that the detection device of the present invention may be used to mon-

itor for leakage and/or hyperinflation during the operation of a known HFO ventilator in addition or as an alternative to monitoring for a spontaneous breathing effort.

Claims

1. A patient ventilator system (19) comprising a high frequency oscillation ventilator (1,4,5,6) connectable to a patient circuit (2,3) and operable to induce oscillations within gas in the circuit (2,3) at a predetermined high frequency and a gas supply (7) connectable to the patient circuit (2,3) for supplying breathing gas thereto; **characterised in that** the ventilator system further comprises a detection device (14,15,16) adapted to monitor during the operation of the high frequency oscillator ventilator (1,4,5,6) one or both gas pressure and gas flow to detect a variation therein not derived from the induced high frequency oscillations and to output a trigger signal (13) dependent on the detected variation indicating a spontaneous breathing effort; and in that gas supply (7) is operable on receipt of the trigger signal (13) to supply breathing gas into the circuit (2,3) at a level to assist the spontaneous breathing effort.

2. A patient ventilator system as claimed in claim 1 **characterised in that** the detection device (14,15,16) comprises a gas sensor (15,16) adapted to sense one or both of the gas pressure (16) and gas flow (15); and an analyser (14) adapted to receive an output from the gas sensor (15,16) indicative of the correspondingly sensed one or both pressure and flow, to calculate therefrom a corresponding value of mean periodic pressure and/or flow; and to output the trigger signal (13) dependent on a deviation of one or both of the calculated mean periodic pressure and/or flow values from an associated predetermined value.

3. A patient ventilator system as claimed in claim 2 **characterised in that** the gas sensor includes a pressure sensor (16) and in that the analyser (14) is further adapted to calculate a change of deviation of the mean periodic pressure from the predetermined level over a plurality of periods of the predetermined high frequency and to output the trigger signal (13) also dependent on the calculated change.

4. A patient ventilator system as claimed in claim 2 or claim 3 **characterised in that** the analyser (14) is adapted to calculate a ratio of inspiratory tidal volume to expiratory tidal volume and to output a trigger signal (13) also dependent on the ratio.

5. A patient ventilator system as claimed in any preceding claim **characterised in that** the high frequency oscillation ventilator (1,4,5,6) is operable to prevent the induction of the high frequency oscillations on receipt of the trigger signal (13).

6. A detection device (14,15,16) operable with a high frequency oscillation ventilator (1,4,5,6) and comprising a gas sensor (15,16) adapted to sense one or both gas pressure (16) and gas flow (15) and an analyser (14) operably connectable to the gas sensor (15,16) to receive an output therefrom indicative of the sensed one or both gas pressure and gas flow and adapted to analyse the output to detect a variation therein not derived from oscillations induced by the ventilator at a predetermined high frequency and to provide an output signal (13,18) dependent on the detected variation.

7. A detection device as claimed in claim 6 **characterised in that** the analyser (14) is adapted to determine a value for one or both mean periodic gas pressure and mean periodic gas flow from the received output and to provide the output signal (13,18) dependent on a deviation of the determined value from an associated predetermined value.

8. A detection device as claimed in claim 7 **characterised in that** the analyser (14) is adapted to determine a change in deviation of one or both of the mean periodic gas pressure and gas flow from a predetermined level over a plurality of periods of the predetermined high frequency and to provide the output signal (13,18) dependent on the determined change.

9. A detection device as claimed in any of the claims 6 to 8 **characterised in that** the analyser (14) is adapted to provide the output signal (13) having at least a component indicative of the detection of a spontaneous breathing effort of a patient.

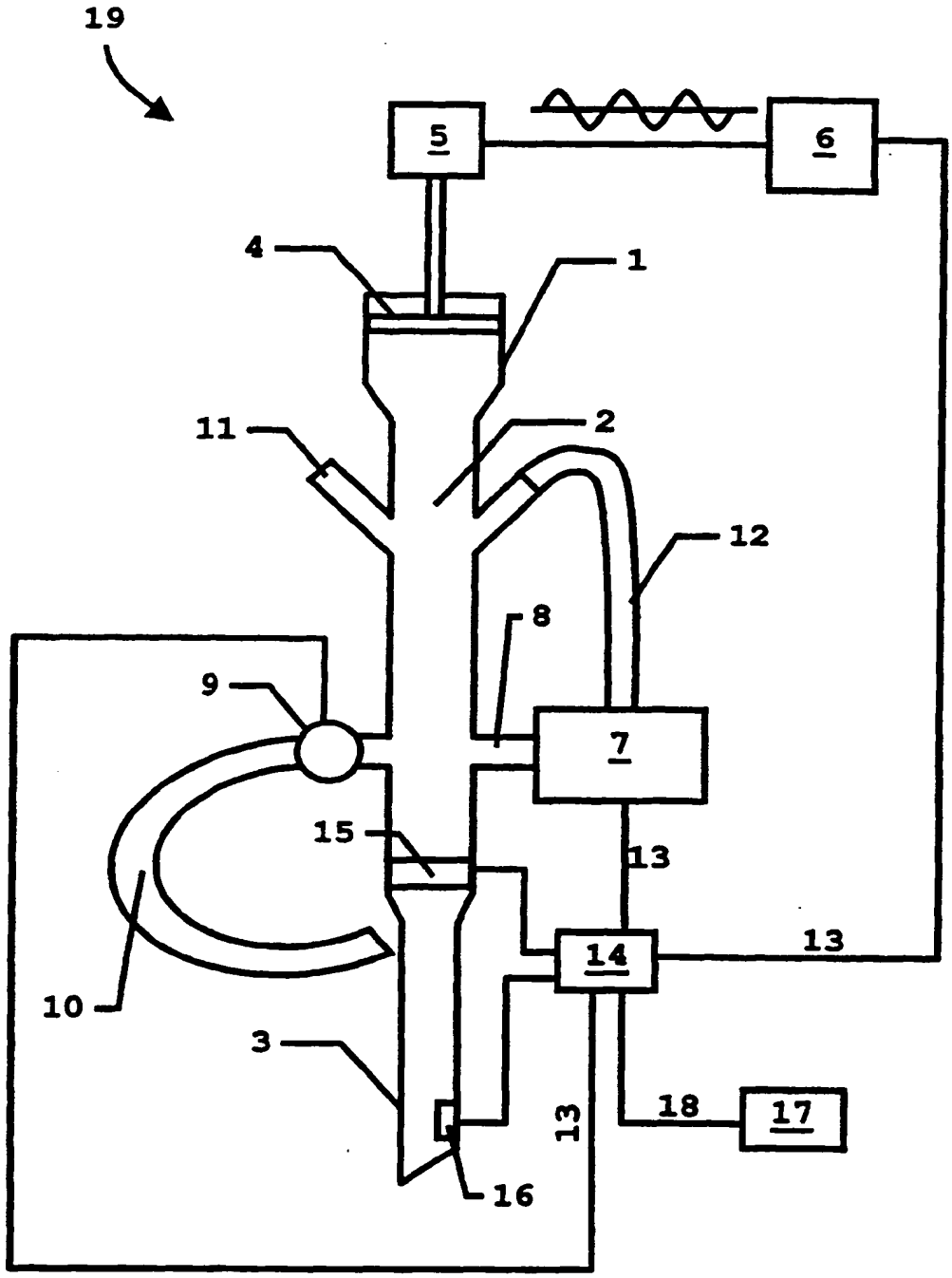

Fig. 1

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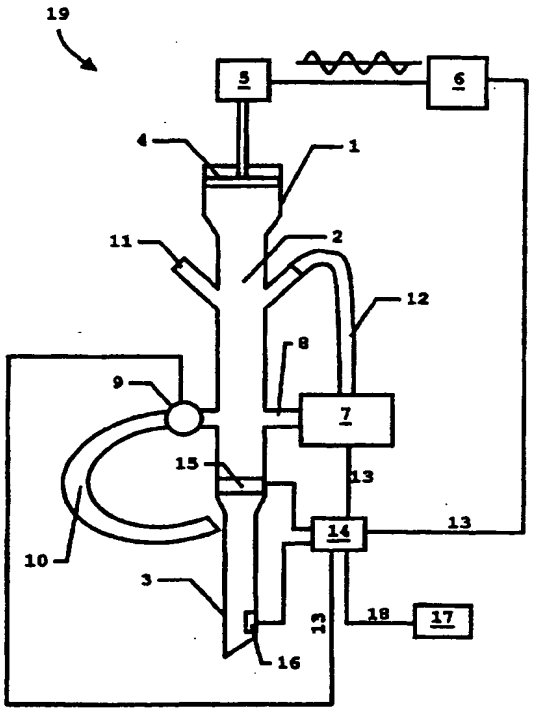

Fig. 1

EP 1 106 197 A3

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Application Number
EP 00 12 0983

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
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A	US 4 838 259 A (GLUCK ERIC H ET AL) 13 June 1989 (1989-06-13) * column 3, line 5 - column 4, line 49 * * column 7, line 51 - line 68; figure 1 *	4	
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TECHNICAL FIELDS SEARCHED (Int.Cl.7)

A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	21 November 2002	Kroeders, M

CATEGORY OF CITED DOCUMENTS

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